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1400 K Street, NW • Washington, DC 20005 • tel (202) 682-4800 • fax (202) 682-4854 • www.rma.org

July 19, 2004

Dr. C. W. Jameson
National Toxicology Program
Report on Carcinogens
79 Alexander Drive
Building 4401
Room 3118
PO Box 12233
Research Triangle Park, NC 27709

RE: 69 FR 28940: National Toxicology Program; Call for Public Comments on 21 Substances, Mixtures and Exposure Circumstances Proposed for Listing in the Report on Carcinogens, Twelfth Edition

Dear Dr. Jameson:

The Rubber Manufacturers Association (“RMA”) and its tire manufacturing members is pleased to comment on the consideration for possible listing in the upcoming Report on Carcinogens by the National Toxicology Program (“NTP”) as published in the Federal Register of May 19, 2004. Our members use talc in their manufacturing processes and have a substantial interest in its potential listing.

The Rubber Manufacturers Association is the national trade association for the rubber products industry. Its members include more than 100 companies that manufacture various rubber products, including tires, hoses, belts, seals, molded goods, and other finished rubber products. RMA members employ over 120,000 workers and account for more than \$21 billion in annual sales.

The NTP deferred consideration of listing talc (asbestiform and non-asbestiform) in the 10th Report on Carcinogens (RoC) due to confusion in the scientific literature over the mineral nature of talc. The NTP has now decided to characterize talc exposure as cosmetic talc and occupational exposure to talc with no distinction between asbestiform and non-asbestiform. The NTP has further proposed to conduct a review on the basis that human epidemiological studies reporting an increase of cancer in workers exposed to talc. The RMA contends that there are no compelling reasons to review talc at this time.

The RMA takes this position for a number of reasons. First, the current NTP characterization seems to ignore the potential contribution of asbestiform fibers to cancer risk. It is also contradictory to the characterizations used by the International Agency for

Research on Cancer (IARC) ¹ and the American Conference of Governmental Industrial Hygienists (ACGIH) ² for talc. Both IARC and ACGIH recognize the etiological differences between asbestiform and non-asbestiform fibers.

Second, the basis for conducting the review does not appear to be supported by three recent human epidemiological studies of talc miners and millers, conducted in Italy ³, Japan ⁴, France and Austria ⁵.

Third, from an alternative perspective, a recent article ⁶ confirms that the practice of using talc as a treatment that is applied directly to the lining of the lung remains the internationally accepted treatment of choice for certain diseases of the lining of the lung – and has been for nearly 100 years. No studies have indicated any increased risk of the development of lung cancer in patients receiving talc application to the lining of the lung.

In summary, the current literature does not support either the NTP characterization or basis for review. Thus, the RMA believes that there is very little to be gained from reviewing talc at this time. We urge the NTP Executive Committee to reject the nomination to list talc in the twelfth Report on Carcinogens.

Sincerely,

Kim Weber
Director, Government Affairs

¹IARC Monograph Silica and Some Silicates. 1987; 42:185 and Supplement 7:349

²ACGIH Threshold Limit Values 2004

³An update of a mortality study of talc miners and millers in Italy. Am J Ind Med. 2003 July; 44(1); 63-9

⁴Mortality among workers at a talc mining and milling facility. Ann Occup Hyg. 2002 Oct;46(7):575-85

⁵A cohort mortality and nested case-control study of French and Austrian talc workers. Occup Environ Med. 2002 Feb; 59(2):98-105

⁶An audit of medical thoracoscopy and talc poudrage for pneumothorax prevention in advanced COPD. Chest. 2004 Apr; 125(4):1190-2